

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-35 (canceled)

Claim 36 (currently amended): A method of treating a human patient suffering from a disease or condition comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, 1.0 mg up to about 1.5 mg of paclitaxel/kg body weight of the patient, wherein the dose for a single administration is between 0.275 and 1.65 mg of paclitaxel/kg body weight of the patient, and wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claims 37 and 38 (canceled)

Claim 39 (currently amended): The method of claim 37, wherein the monthly dose is about 1 to about 7.5 mg/paclitaxel/kg body weight.

Claims 40 and 41 (canceled)

Claim 42 (previously presented): The method of claim 36, wherein administering the cationic liposomal preparation comprises administering a plurality of times during a month period, and wherein each administration is separated by an interval of between one day and 3 weeks.

Claim 43 (previously presented): The method of claim 36, wherein administering the cationic liposomal preparation comprises administering

- (i) at least 3 times or 3-5 times in a first week, followed by an interval of 1-3 weeks without administration, and optionally one or several repeats of this protocol;
- (ii) once in a first week followed by an interval of at least one week or 1-3 weeks, without administration, and optionally one or several repeats of this protocol;
- (iii) once in a week for one week or several successive weeks; or
- (iv) a combination of (i), (ii) and/or (iii).

Claim 44 (currently amended): A method of treating a human patient suffering from a disease or condition with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about ~~0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, 1.0 mg up to about 15 mg of paclitaxel/kg body weight of the patient, wherein the dose for a single administration is between 0.275 and 1.65 mg of paclitaxel/kg body weight of the patient, and~~ wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy.

Claim 45 (previously presented): The method of claim 44, wherein the composition is administered simultaneously with an effective dose of at least one further active agent.

Claim 46 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of at least about 2 mole% to about 8 mole%.

Claim 47 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of about 2.5 mole% to about 3.5 mole%.

Claim 48 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 49 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises substantially no paclitaxel crystals.

Claim 50 (previously presented): The method of claim 36, wherein the condition is an angiogenesis-associated condition.

Claim 51 (previously presented): The method of claim 50, wherein the disease or condition is selected from the group consisting of cancer, rheumatoid arthritis, dermatitis, psoriasis and endometriosis.

Claim 52 (currently amended): A method of treating or preventing a disorder associated with and/or accompanied by occurrence of drug resistant cells, ~~such as drug-resistant tumors~~ comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of ~~about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, 1.0 mg up to about 15 mg of paclitaxel/kg body weight of the patient, wherein the dose for a single administration is between 0.275 and 1.65 mg of paclitaxel/kg body weight of the patient, and~~ wherein the pharmaceutical composition comprises at least one cationic lipid from about 30 mole% to about 99.9 mole%, ~~an active agent, paclitaxel~~ in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 53 (previously presented): The method of claim 52, wherein the method is a second or third line treatment for cancer.

Claim 54 (previously presented): The method of claim 52, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 55 (currently amended): A method of treating or preventing metastasis formation in a human patient, comprising administering a pharmaceutical composition at a monthly dose of ~~about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, 1.0 mg up to about 15 mg of paclitaxel/kg body weight of the patient, wherein the dose for a single administration is between 0.275 and 1.65 mg of paclitaxel/kg body weight of the patient, and~~ wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one

cationic lipid from about 30 mole% to about 99.9 mole%, ~~an active agent~~ paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 56 (previously presented): The method of claim 55, wherein the method treats or prevents liver metastasis formation.

Claim 57 (currently amended): A method of treating a human patient with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, 1.0 mg up to about 15 mg of paclitaxel/kg body weight of the patient, wherein the dose for a single administration is between 0.275 and 1.65 mg of paclitaxel/kg body weight of the patient, and wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, ~~an active agent~~ paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy against metastasis onset and/or progression, ~~e.g.,~~ associated with and/or accompanied by the tumors.

Claim 58 (previously presented): The method of claim 57, wherein the composition is administered simultaneously with an effective dose of at least one further active agent.

Claim 59 (currently amended): The method of claim ~~52~~58, wherein the further active agent is selected from the group consisting of a cytotoxic or cytostatic substance ~~such as an anti-tumor or an anti-endothelial cell active substance~~, a chemotherapeutic agent ~~or~~ and an immunological active substance.

Claim 60 (previously presented): The method of claim 55, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 61 (canceled)

Claim 62 (currently amended): The method of claim 44, wherein the further active agent is selected from the group consisting of an anti-endothelial cell active substance, an anti-tumor active substance, a chemotherapeutic agent, an immunological active substance, a compound that reduces or eliminates hypersensitivity reactions ~~or~~ and a chemosensitizer.

Claim 63 (currently amended): The method of claim 44, wherein the further active agent is ~~selected from the group consisting of~~ an antineoplastic agents especially antimitotic agents like paclitaxel, cisplatin, carboplatin, camptothecin, doxorubicin, 5-fluorouracil and gemcitabine.

Claim 64 (withdrawn): The method of claim 62, wherein the compound that reduces or eliminates hypersensitivity reactions is selected from the group consisting of steroids, antihistamines, H2 receptor antagonists, and combinations thereof in a sufficient amount to prevent fatal anaphylactic reactions.

Claim 65 (withdrawn): The method of claim 63, wherein the compound is selected from the group consisting of Ranitidine, Dexamethasone, Diphenhydramine, Famotidine, Hydrocortisone, Clemastine, Cimetidine, Prednisolone, Chlorpheniramine, Chlorphenamine, Dimethindene maleate, and Promethazine.

Claim 66 (withdrawn): The method of claim 62, wherein the chemosensitizer is selected from the group consisting of cell cycle modulators, substances that revert a drug resistance like verapamil, vasoactive substances like anti-hypertensive drugs, and substances that modify interactions of cationic liposomes with blood components like protamine.

Claim 67 (previously presented): The method of claim 36 for the treatment of cancer, wherein the disease is selected from the group consisting of pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma.

Claim 68 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises liposomes having an average particle diameter from about 25 nm to about 500 nm, preferably about 100 nm to about 300 nm.

Claim 69 (previously presented): The method of claim 36, wherein the cationic liposomal preparation is administered intravenously.

Claims 70 and 71 (canceled)

Claim 72 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 73 (previously presented): The method of claim 44, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 74 (previously presented): The method of claim 52, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 75 (previously presented): The method of claim 55, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 76 (previously presented): The method of claim 57, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 77 (previously presented): The method of claim 70, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 78 (new): The method of claim 63, wherein the antineoplastic agent is an antimitotic agent.

Claim 79 (new): The method of claim 78, wherein the antimitotic agent is selected from the group consisting of cisplatin, carboplatin, camptothecin doxorubicin, 5-fluorouracil and gemcitabine.